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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
BDBI-001/01US

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Typed or printed name _____

Application Number	Filed
10/087,217	March 4,2002

First Named Inventor
Yong YAO

Art Unit	Examiner
1649	John D. Ulm

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant/inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [ ] attorney or agent of record. Registration number _____
- [X] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Bonnie Weiss McLeod
Signature

Bonnie Weiss McLeod
Typed or printed name

(202) 842-7800
Telephone number

March 29, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

[X] *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

Dated: March 29, 2006

Respectfully submitted,
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OIPE IAP13
MAR 29 2006
PATENT & TRADEMARK OFFICE

PATENT
ATTORNEY DOCKET NO.: BDBI-001/01US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of:	)	
	)	
Yong YAO *et al.*	)	Confirmation No.: 2158
	)	
Application No.: 10/087,217	)	Group Art Unit: 1649
	)	
Filed: March 4, 2002	)	Examiner: John D. ULM
	)	
FOR: NOVEL CELL-BASED ASSAYS FOR G-PROTEIN COUPLED RECEPTOR-MEDIATED ACTIVITIES	)	

Commissioner for Patents
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Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

This Pre-Appeal Brief Request is filed in response to the final Office Action dated January 6, 2006. Pursuant to the requirements set forth in the Official Gazette (12 July 2005), this Request is filed concurrently with a Notice of Appeal and prior to the filing of an Appeal Brief. Review and reconsideration of the rejection under 35 U.S.C. §112, first paragraph is respectfully requested.

In the final Office Action dated January 6, 2006, claims 22-24, 26, 28-41, 43-45, 47, 49-62, 64-67, 69, 71, 73-82 and 103-105 (all pending claims) were rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner alleges that the claims are not enabled by the specification because they allegedly omit a step or element that is essential or critical to the practice of the invention. Specifically, the Examiner asserts that an artisan cannot attribute a

measured channel activity to a specific G protein coupled receptor in the absence of a comparative step that employs a cell that is otherwise identical to the test cell except for the absence of receptor protein of interest, *i.e.*, a negative control (p. 2 of Action dated January 6, 2006). The Examiner then concludes that "the claims are not enabled because the instant specification does not provide the guidance needed to practice the claimed method without employing such a comparative step" (p. 3, lines 1-3). The Examiner has acknowledged that the use of a negative control for a G coupled protein receptor was known in the art (see Office Action dated June 13, 2005, p. 3, "the use of such controls is certainly well known in the art"). However, the Examiner contends that "the fact that one of ordinary skill would recognize the need for a [control] only supports the position that such a step is essential to the assay and therefore, must be included as a recited claim element" (paragraph bridging pps. 3-4 of the Office Action dated January 6, 2006).

The Examiner relies on *In re Mayhew*, 188 USPQ 356 (CCPA 1976), and MPEP 2172.01 (see Office Action dated Dec. 27, 2004), for the position that the present claims are not enabled because they omit a step or element that is critical to the invention. The Examiner's reliance on *In re Mayhew* and MPEP 2172.01 is misplaced. According to MPEP 2172.01:

> A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under 35 U.S.C. 112, first paragraph, as not enabling. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). See also MPEP § 2164.08(c). Such essential matter may include missing elements, steps or necessary structural cooperative relationships of elements described by the applicant(s) as necessary to practice the invention. (With emphasis.)

Similarly, as stated in MPEP 2164.08:

> A feature which is taught as critical in a specification and is not recited in the claims should result in a rejection of such claim under the enablement provision

> section of 35 U.S.C. 112. See *In re Mayhew*, 527 F.2d 1229, 1233, 188 USPQ 356, 358 (CCPA 1976) . . . an enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended. Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality.

At no point in the specification or during prosecution do Applicants state that a negative control is critical for the claimed method to be performed as specified in the MPEP provisions quoted above. Applicants have not asserted that the skilled artisan "would recognize the need for" a control as asserted by the Examiner (Office Action dated January 6, 2006, p. 6). Rather, Applicants have only noted that the use of such controls is well known and routine in the art. In fact, as stated in the 1.132 declaration by Xiao Li, an expert in the field, "it was well known in the art that a negative control is not always necessary, for instance where the host cell is known not to express relevant endogenous GPCRs" (see paragraph 3 of Li declaration, filed October 13, 2005) (with emphasis).

The Examiner has responded to the Li declaration by asserting that the claims are not limited to the use of host cells that are known not to express relevant endogenous GPCRs, and that the instant specification fails to identify such cells (p. 3 of Office Action dated January 6, 2006). Yet it is self-evident that the skilled artisan practicing the invention would not chose to use a cell line that expresses interfering endogenous GPCRs. *See In re Mayhem*, 188 USPQ at 359 ("We think it self-evident that the function of the cooling zone is simply to cool the strip . . . and we feel that a statement of function would be superfluous.") (with emphasis).

Indeed, claim 22 is directed to a method of detecting activity of a GPCR comprising a step wherein the GPCR is expressed in a cell from an exogenous nucleic acid. Similarly, claim 43 is directed to a method of identifying a ligand for a GPCR and involves the use of a cell

expressing the GPCR wherein the GPCR is not endogenous to the cell. It is self-evident that the skilled artisan, in choosing an appropriate host cell for the claimed methods, would not chose a cell that expresses interfering endogenous GPCRs. Thus, the negative control described in the Office Action would not be critical in these artificial systems.

Claim 64 is directed to a method of identifying a putative agent that modulates an activity mediated by a GPCR, *i.e.*, characterizing an orphan receptor whose specificity is not known. It would be clear to the skilled artisan that a negative control is not necessary to identify a putative agent. To comply with §112, first paragraph, it is not necessary to "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) (*see also* MPEP 2164).

In any case, as noted in MPEP 2164.01, the appropriate standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde,* 242 U.S. 261, 270 (1916), which postured the question: is the experimentation needed to practice the invention undue or unreasonable? Further, the Federal Circuit has made it clear that a patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). The Examiner has applied an incorrect standard in his application of the enablement requirement, inappropriately akin to what one might encounter in the review of a scientific journal article rather than a patent examination. Indeed, as noted above, the Examiner has acknowledged that the use of negative controls was well known in the art. Accordingly, the design of such negative controls, when warranted, could not possibly rise to the level of undue experimentation.

In light of these remarks, Applicants respectfully request reconsideration and withdrawal of the rejection under §112, first paragraph.

Applicants note that there are two minor rejections under §112, second paragraph that were also set forth in the final Office Action (p. 4). These rejections could easily be resolved by Examiner's amendment should the Panel decide to withdraw the §112, first paragraph rejection. For instance, claims 22, 43 and 64 could be readily amended to replace the plural "signals" with the singular "signal." Secondly, claims 39, 60 and 82 could be readily amended to specify that the promiscuous G protein interacts with the GPCR, as disclosed in the specification at page 21, lines 3-4 and page 25, lines 20-29. It is Applicants' understanding that, in appropriate circumstances, a proposed amendment may accompany the Panel's decision proposing changes that, if accepted, may result in an indication of allowability for the contested claims (OG, 12 July 2005, section 6).

If the Examiner or the Panel have any questions relating to this Request or to the application in general, they are encouraged to contact the undersigned by telephone so that allowance of the present application may be expedited.

Respectfully submitted,

COOLEY GODWARD LLP

Date: March 29, 2006 By: _____

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